

PTO-1390 (Rev. 07-2005)

Approved for use through 3/31/2007. OMB 0651-0021 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

ATTORNEY'S DOCKET NUMBER WH-18 U.S. APPLICATIONING. (IF PRIORITY DATE CLAIMED November 20, 2003

**CONCERNING A SUBMISSION UNDER 35 U.S.C. 371** INTERNATIONAL APPLICATION NO. PCT/IN2004/000347 INTERNATIONAL FILING DATE November 10, 2004 TITLE OF INVENTION NOVEL POLYMORPHS OF RACEMIC, DEXTROROTATORY, AND LEVOROTATORY ENANTIONERS OF 1-CYCLOPROPYL-6-FLUORO-8-METHOXY-7-(4-AMINO-3,3-DIMETHYLPIPERIDIN 1-YL)-1,4-DIHYDRO-4-OXO-QUINOLINE-3-CARBOXYLIC ACID HYDROCHLORIDE AND MESYLATE SALTS APPLICANT(S) FOR DO/EO/US Prasad Keshav DESHPANDE, Satish Baliram BHAVSAR, Yati CHUGH, Ravindra Dattatrya YEOLE, Noel John DE SOUZA, and Mahesh Vithalbhai PATEL Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information: 1. X This is a FIRST submission of items concerning a submission under 35 U.S.C. 371. This is a SECOND or SUBSEQUENT submission of items concerning a submission under 35 U.S.C. 371. This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below. The US has been elected (Article 31). A copy of the International Application as filed (35 U.S.C. 371(c)(2)) is attached hereto (required only if not communicated by the International Bureau). has been communicated by the International Bureau. is not required, as the application was filed in the United States Receiving Office (RO/US). An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)). is attached hereto. has been previously submitted under 35 U.S.C. 154(d)(4). Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) are attached hereto (required only if not communicated by the International Bureau). have been communicated by the International Bureau. have not been made; however, the time limit for making such amendments has NOT expired. have not been made and will not be made. An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)). Items 11 to 20 below concern document(s) or information included: 11. X An Information Disclosure Statement under 37 CFR 1.97 and 1.98. An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. A preliminary amendment. An Application Data Sheet under 37 CFR 1.76. A substitute specification. 140 16 X A power of attorney and/or change of address letter. 🚱 A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821- 1.825. A second copy of the published International Application under 35 U.S.C. 154(d)(4). A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).

This collection of information is required by 37 CFR 1.414 and 1.491-1.492. The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 15 minutes to complete, including gathering information, preparing, and submitting the completed form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450. Page 1 of 3

PTC-1390 (Rev. 07-2005)
Approved for use through 3/31/2007. OMB 0651-0021
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Not assigned	10/57	8371	PCT/IN2004/000347	PEICATION NO.	WH-18	CRET NUMBER	
20. Other items or information:							
1. Credit Card Payment form (one page). 2. International Search Report (6 pages). 3. Written Opinion of the International Searching Authority (7 pages).							
The follow	wing fees have b	een submitted			CALCULATIONS	PTO USE ONLY	
21. Basic national fee (37 CFR 1.492(a)) \$300					\$ 300.00		
	nation fee (37 CF	R 1 492(c))					
If the written opinion by IPEA/U	on prepared by IS IS indicates all cl	s 200.00					
All other situations	s .						
23. Search fee (37 CFR 1.492(b))  If the written opinion of the ISA/US or the International preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) \$0  Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority					\$ 500.00		
-	OTAL OF 24 22				1000.00		
TOTAL OF 21, 22 and 23 =  Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(j)).  The fee is \$250 for each additional 50 sheets of paper or fraction thereof.							
Total Sheets	Extra Sheets	ra Sheets Number of each additional 50 or fraction thereof (round up to a whole number)					
99 <sub>- 100</sub> =   0.0 <sub>/50</sub> =				x \$250	\$ 0.0	1	
Surcharge of \$130.00 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)).					\$		
CLAIMS	NUMB	ER FILED	NUMBER EXTRA	RATE	\$		
Total claims		56 - 20 =	36	x \$ 50	s 1800.00		
Independent claim	ns	14 -3=	11	x \$200	\$ 2200		
MULTIPLE DEPENDENT CLAIM(S) (if applicable) + \$360					\$ 0.0		
TOTAL OF ABOVE CALCULATIONS =					\$ 5000.00		
Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by ½.							
SUBTOTAL =					\$ 5000.00		
Processing fee of claimed priority da		\$					
		\$					
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property +					\$		
-		s 5000.00					
					Amount to be refunded:	\$	
					Amount to be charged	\$	

10/578371

PTO-1390 (Rev. 07-2005)
Approved for use through 3/31/2007. OMB 0651-0021
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

a. A check in the amount of \$  b. Please charge my Deposit Account No A duplicate copy of this sheet is enclosed.		
c. The Commissioner is hereby authorized to charge Account No A duplicate copy of the	is sheet is enclosed.  G: Information on this form ma ormation and authorization on  495 has not been met, a peti	
SEND ALL CORRESPONDENCE TO:  Bio Intellectual Property Service (BIO IPS) LLC 8509 Kernon Ct, Lorton, VA 22079. USA Cell Phone (703-919-4348), Fax: (703-550-0409) (703) 550-1968 (Voice/Fax) BioIPS@BioIPs.com (E-mail)		SIGNATURE Dr. O. M. (Sam) Zaghmout NAME 51,286 REGISTRATION NUMBER

# **10/578371**IAP12 Reg'd PCT/PTO 05 MAY 2006

PATENT
Client Reference Number: WH-18

#### CERTIFICATE OF HAND DELIVERY

I hereby certify that this correspondence is being hand filed with the United States Patent and Trademark Office in Washington, DC. 20231

on May 5, 2006 (Date)

Typed or printed name of person signing this certificate

Attachments:

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#### **Applicants:**

Prasad Keshav DESHPANDE, Satish Baliram BHAVSAR, Yati CHUGH, Ravindra Dattatrya YEOLE, Noel John DE SOUZA, Mahesh Vithalbhai PATEL

Title: NOVEL POLYMORPHS OF RACEMIC, DEXTROROTATORY, AND LEVOROTATORY ENANTIONERS OF 1-CYCLOPROPYL-6-FLUORO-8-METHOXY-7-(4-AMINO-3,3-DIMETHYLPIPERIDIN-1-YL)-1,4-DIHYDRO-4-OXO-QUINOLINE-3-CARBOXYLIC ACID HYDROCHLORIDE AND MESYLATE

Filing Date: Not assigned.

Application Serial Number: Not assigned.

Examiner: Not assigned.

Confirmation Number: Not assigned.

Mail Stop: PCT

Date: May 04, 2006

## **New National Stage Patent application**

Honorable Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

Attached herewith for filing is a 99-page patent specification including 56 claims, and an abstract. The specification constitutes the application of DESHPANDE et al. for the captioned invention.

This application claims the benefit of International Patent Application No. PCT/IB2004/000347, filed November 10, 2004 which claims priority to 1199/MUM/2003, filed

1 of 2. 6:23 PM. 5/4/2006. New National Stage Patent Application.

Applicants: DESHPANDE et al.

Title: NOVEL POLYMORPHS OF RACEMIC, DEXTROROTATORY, AND LEVOROTATORY ENANTIONERS OF 1-CYCLOPROPYL-6-FLUORO-8-METHOXY-7-(4-AMINO-3,3-DIMETHYLPIPERIDIN-1-YL)-1,4-

DIHYDRO-4-OXO-QUINOLINE-3-CARBOXYLIC ACID HYDROCHLORIDE AND MESYLATE

Mail Stop: PCT. Our reference number: WH-18.

10/5783/1 IAP12 Rec'd PCT/PTO J5 MAY 2006

November 20 2003. This new national stage patent application also claims priority to US patent provisional application No. 60/523,872. The entire disclosure of the prior applications are hereby incorporated by reference.

In addition, the followings are attached:

- 1. PTO -1390 (2 pages).
- 2. A copy of the published PCT/IB2004/000347.
- 3. Declaration and Power of attorney.
- 4. Information Disclosure Statement and copy of a reference.
- 5. A credit card payment form.

#### **CONCLUSION**

Applicants respectfully request favorable consideration of the present application and a timely examination of the pending claims.

Should any official at the United States Patent and Trademark Office deem that any further action by the Applicant or Applicant's undersigned representative is desirable and/or necessary, the official is invited to telephone the undersigned at the number set forth below.

Respectfully submitted,

By: Sam Zaglimout

O. M. (Sam) Zaghmout Ph.D (Registration No. 51,286)

### **Contact Information:**

Bio Intellectual Property Service (BIO IPS) 8509 Kernon Ct, Lorton, VA 22079. USA Cell Phone (703-919-4348), Fax: (703-550-0409) (703) 550-1968 (Voice/Fax) AP3 Rec'd PCT/PTO 35 MAY 2008

10/578371

The PTO did not receive the following listed item(s)

NO POST CARD